



April 19, 2001

Chicago District  
300 S. Riverside Plaza, Suite 550 South  
Chicago, Illinois 60606  
Telephone: 312-353-5863

**WARNING LETTER**  
**CHI-29-01**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Denis P. Ryan, President  
First Season, Inc.  
2254 North Elston Avenue  
Chicago, IL 60614

Dear Mr. Ryan:

On March 6, 7, 12 & 16, 2001, the Food and Drug Administration (FDA) conducted an inspection of your orange juice manufacturing facility. During the inspection, original labels for "HIPPO JUICES FRESH SQUEEZED ORANGE JUICE" were collected. Review of this product label, which our investigator determined is used on orange juice you manufacture, found a serious violation of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations, Part 101 (21 CFR 101), with regard to labeling of food products.

The above-identified product is misbranded within the meaning of Section 403(a)(1) and 201(n) of the Act. It is misbranded because it does not comply with the labeling requirement that juices not specifically processed to prevent, reduce or eliminate the presence of pathogens bear the warning statement set forth in 21 CFR 101.17.

The above violation concerns certain labeling requirements, and is not meant to be all-inclusive regarding deficiencies that exist in your labels. Other labeling violations can subject the food to legal action.

It is your responsibility to assure that all your products are labeled in compliance with all applicable statutes enforced by the FDA.

You should take prompt action to correct the violation identified above. Failure to promptly correct this violation may result in regulatory action without further notice. This action may include seizure and/or injunction.

Page 2

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violation. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

Your reply should be directed to James T. Karpus, Compliance Officer, at the address indicated in the letterhead.

Sincerely,

\s\  
Raymond V. Mlecko  
District Director